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14. ABSTRACT
Part 1 of the 3 part study was conducted on 13 May 2009 at Nationwide Children's Hospital. This was a cadaver cohort study with video comparison between radiologists with percutaneous USFBR, conventional surgical foreign body removal, and surgical foreign body removal with wire localization comparing incision size, time of procedure, wound closure (number of sutures), overall removal success and procedural differences. In this component, comparison data was collected using human cadaver thighs for testing differences between the surgical and percutaneous techniques. Part 1 was completed with success in year 1 using the tasks described in the approved SOW. The hypothesis for part 1 was proven partially correct. The hypothesis was that ultrasound guided foreign body removal (USFBR) is faster and more effective than open surgical removal, with smaller incisions. The results found that USFBR is more effective than open surgical removal, with smaller incisions. However the results also showed that the surgical method was faster. No progress was made in year 2 so year 3 we will proceed with part 2 training and part 3 clinical implementation as described in the approved SOW.

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INTRODUCTION:

This is a three part study: Part 1 is a cadaver cohort study with video comparison between radiologists with percutaneous ultrasound guided foreign body removal (USFBR), conventional surgical foreign body removal, and wire localization followed by surgical foreign body removal, comparing incision size, time of procedure, wound closure (number of sutures), overall removal success and procedural differences. Part 2 is an educational efficacy research project. The physicians are trained with a turkey breast simulator. They will be evaluated and measured on their performance and competency development with USFBR. Part 3 is a clinical implementation of USFBR in military health care setting as part of patient care of wounded war fighters with symptomatic soft tissue foreign bodies retained after blast injuries.

BODY:

As previously reported in the first annual report, Part 1 of the 3 part study was conducted on 13 May 2009 at Nationwide Children's Hospital (NCH). All of part 1 was completed in year 1. This was a cadaver cohort study with video comparison between radiologists with percutaneous USFBR, conventional surgical foreign body removal, and surgical foreign body removal with wire localization comparing incision size, time of procedure, wound closure (number of sutures), overall removal success and procedural differences. In this component, comparison data was collected using human cadaver thighs for testing differences between the surgical and percutaneous techniques. Procedures were videotaped for a detailed analysis and accurate documentation of major and minor procedural differences. Statistical analysis projected 9 removals per procedures type would provide complete data sets for demonstration of statistical significance. Local IRB at NCH and secondary IRB approval through DOD ORP HRPO were obtained. Part 1 was completed with success in year 1 using the tasks described in the approved SOW.

The PI, William E. Shiels II, DO (Radiologist) implanted a total of 27 foreign bodies into human cadaver tissue. The anatomical materials used were human cadaver thighs. To remain consistent, all foreign bodies were the same. A 1 cm piece of a wooden toothpick was used to represent a traditional foreign body implanted in the cadaver tissue. Each cadaver thigh had 3 foreign bodies positioned into the tissue by Dr. Shiels. The study coordinator, Beth M. Haeuptle, MA timed, observed and documented the foreign body removals. Brad Hoehne (Graphic Animation Artist) had 2 digital video cameras on tripods documenting the procedures. He also hand held a high powered video camera which allowed for close up video to substantiate the findings. This same footage was used to develop future training materials in part 2 of the 3 part study. Dr. Shiels monitored the research efforts. Brian D. Kenney MD (surgeon) and James W. Murakami, MD (Radiologist) performing the foreign body removals; both physicians self-reported the start and end time, the incision size, number of sutures as well as the success or failure of the foreign body removal. This was done in conjunction with the written and video documentation for accuracy of findings.

Using a traditional surgical method following the skin marking of the foreign body location, Brian D. Kenney, MD completed 9 foreign body removals (3 in each thigh). The incision size for each removal ranged from 30mm – 58mm with a mean of 45.78 mm. The number of sutures ranged from 4 to 9 in order to effectively close the wound. The time to complete the procedure (skin to skin time) ranged from 4-15 minutes with a mean of 8.33 min.; 7 of the 9 removal attempts were successful. One foreign body was unable to be located by the surgeon. In a live situation the surgeon would send the patient to Radiology for wire localization and then the surgeon would re-operate with the wire localization method or percutaneous ultrasound guided foreign body removal would be completed by a Radiologist.

Dr. William E. Shiels II, DO used ultrasound guidance for placement of localization wires at the site of each of 9 foreign bodies (3 in each thigh). Brian D. Kenney, MD then used an operative method following the wire localization to remove the foreign bodies. The incision size for each removal ranged from 24mm – 39mm with a mean of 32.1 mm. The number of sutures ranged from 3 to 6 in order to effectively close the wound. The time to complete the procedure (skin to skin time) ranged from 4-12 minutes with a mean of 7.1 min.; 8 of the 9 removals were successful. One foreign body was unable to be located by the surgeon.

The third removal type was percutaneous interventional radiological ultrasound guided foreign body removal. The technique was performed by James W. Murakami, MD. He completed 9 foreign body removals (3 in each thigh). The incision size for each removal ranged from 5mm – 9mm with a mean of 6.4 mm. Sutures are not needed for this removal technique due to the minimal incision size. A Band-Aid placed over the wound is standard of care. The time to complete the procedure (skin to skin time) ranged from 3-26 minutes with a mean of 12.2 min.; all 9 percutaneous removals were successful.

There are no previously reported findings to compare to our data.

No publications or presentations have been submitted, to date, for this research.

Unforeseen technical issues with cadaver materials occurred with both the surgical and the radiological procedures. The surgeon, Brian D. Kenney, MD commented that operative removal was a much easier in a cadaver compared to a live human because operative sites were not complicated by bleeding. During a procedure with a live patient the surgeon would need to stop every few minutes to manage bleeding which would lengthen the procedure time. During his first removal he commented that "this is necessitating significant tissue destruction to find the foreign body". Additionally, the surgeon felt that blunt dissection facilitated movement of the foreign bodies in the surgical field; the surgeon switched from a blunt dissection to a sharp dissection to alleviate the movement issue. Both the surgeon and the radiologist reported the remarkable amount of movement with the foreign body removal. The surgeon noted that the 3 foreign bodies implanted in the third thigh with the traditional surgical removal were placed in the subcutaneous fat and not the muscle which made locating the foreign body easier. The wooden toothpicks were colored which the surgeon commented helped when searching for the foreign bodies. This is an advantage to the surgical method in the cadaver because the radiological method does not use an open operative field in which to see the color of the toothpick to help with localization. Dr. Kenney also verbalized the learning process of following the fascial penetration site for his operative approach; he said that once he adapted to that technique then the process was simplified. Live human tissue with a foreign body and the time it takes to seek treatment would not leave such an easy hole to follow in order to locate the foreign body. This is seen as an advantage to the operative procedure in a cadaver. With respect to wire localization procedure, Dr. Kenney noted that wire localization made the removal process much easier. The key to success with this method was having an experienced interventional radiologist provide

proper placement of the localization wire. If someone other than an experienced radiologist placed the wire, the failure rate would most likely increase.
The radiologist in this study, Dr. Murakami, has performed over 100 foreign body removal procedures on living patients and expressed that it is was very difficult working with cadaveric material. The mechanical (elastic) properties of the cadaver tissue effect the percutaneous ultrasound guided foreign body removal, seeming to add a degree of difficulty to cadaveric removal not experienced in live humans.

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The findings demonstrated that percutaneous ultrasound guided foreign body removal technique has much less tissue destruction as compared with operative techniques; the incision size is also much smaller with this technique. This would result in a faster healing time if the foreign body removal was performed in a live patient. Sutures are not needed in the radiological method. The success rate was 100% for the percutaneous ultrasound guided foreign body removal technique. Whereas the removal success rate for the traditional surgical method was 78% successful and the surgical with wire localization was 89% successful**.**

Part 2 of the 3 part study is the competency training, testing, and documentation of military physicians in USFBR techniques. The approved SOW documented that this would take place in years 1-3. The unanticipated retirement of the part 2 PI, Les Folio, DO, COL, MC, USAF, SFS slowed down the submission process to the local IRB at USUHS. We worked in year 1 to change the PI to Grant E. Lattin, Jr., MD, MAJ, MC, USAF at USUHS but he later declined. We are currently working with Brooke Army Medical Center (BAMC) to list Anthony W. Allen, MD, COL, MC, USA. COL Allen has verbally agreed to help but will still need to review a revised protocol before he can fully commit to the project. These revisions are presently being completed. A revised SOW will be submitted to TATRC to reflect the change of PI for part 2 as well as the location change from USUHS to NCH after COL Allen reviews the revised protocol and agrees to participate. Upon approval from TATRC the protocol will be submitted to BAMC for local IRB approval as well as local IRB approval at NCH and final approval through the ORP HRPO.

This phase of the research will have formalized and standardized procedural training, with development of clinical guidelines for surgeons as well as radiologists. The changes for part 2 have been discussed and approved verbally with TATRC staff but a formal revision and submission of the SOW to TATRC is planned for the first quarter of year 3 and will need to be approved before proceeding with the study. The changes would include submitting a letter to dissolve the contract with HMJF, complete the process of the change of PI for part 2 from COL Folio to Dr. Shiels, change the location of part 2 to NCH, and list COL Allen as a co-investigator.

The training and testing component was originally subcontracted to HMJF and was originally to be conducted at The Uniformed Services University of The Health Sciences (USUHS). The revised SOW that will be sent to TATRC in the first quarter of year three will propose that the training now be conducted at NCH with Dr. Shiels as PI and list Dr. Allen as a co-investigator at BMAC. Dr. Shiels will be performing all training and testing (and collecting data), with LTC Allen serving as the co-investigator at BMAC to assist in the recruitment of Army physicians. Training will be performed quarterly for military physicians (maximum of six physicians each session), was originally planned over a 3 year period. Since we are 2 years behind and have not used the travel or training funds in the budget we anticipate pursuing optional future years if funding is available due to the delay in starting parts 2 and 3. This extension to the 3 year award will be requested later in year 3 once all the revisions and submissions have been approved. Since the unexpected retirement of the PI for part 2 delayed the start of the project and no funds have been spent for part 2 then the optional years for an extension of time is all that will be requested without affecting the research protocol but simply to allow for recruitment to conduct the original study.

Competency testing and training will involve one day of didactic and hand-on training, with pre- test and post- test components. Testing will be include video review of a representative USFBR procedure followed by live procedural pre-testing of each radiologist/physician for removal success, time to removal, demonstration of technical component proficiency, and successful recognition/management of technical pitfalls. Training will include standardized and formalized didactic training materials, which incorporate written, slide presentation, animation, and hands -on tissue model mentored training components. Post-training competency testing will include documentation of successful removal of a minimum of 5 foreign bodies using USFBR techniques, with proper procedural steps and recognition/management of procedural pitfalls.

Part 2: Competency testing, training, and documentation of military radiologists/physicians in USF BR techniques. Sub-contract training component to The Henry Jackson Foundation at The Uniformed Services University of the Health Sciences will be proposed to dissolve the HMJF subcontract and conduct the part 2 training at NCH

I. Standardized percutaneous USFBR training
    1. Session 1
        a. Pretest doctors
            i. Video demonstration of USFBR procedure
            ii. Hands-on pre-training test (15 minutes)
            iii. Written analysis of video documentation detailing the foreign body removal technique
                1. Time to removal
                2. Success/failure of removal attempt after 15 minutes
                3. Proper/errant alignment of insonation and instruments
                4. Proper/errant hand position and transducer position
                5. Proper/errant use of forceps in field of operation
                6. Proper/errant stepwise foreign body definition
                7. Proper/errant forceps grasp of foreign body
                8. Recognition/lack thereof-volume averaging artifact

            9. Recognition/lack thereof-oblique crosscut artifact

   b. Phase one of standardized competency training of percutaneous ultrasound guided soft tissue foreign body removal
      i. Didactic classroom training (Powerpoint discussion with animations)
         1. Essentials of sonography-rationale and scientific basis
            a. Contact scanning
         2. Sonographic foreign body characterization
            a. Wood, metal, glass, plastic, stone/ceramic
         3. Standardized stepwise instruction in USFBR
            a. Includes options for forceps position-vertical vs. horizontal
            b. Forceps open vs. closed
            c. Foreign body definition prior to removal
            d. Blunt dissection vs. sharp dissection
            e. Hydrodissection
         4. Options for instrumentation-forceps
         5. Clinical management following USFBR
         6. Pitfalls
            a. Volume averaging artifact
            b. Oblique crosscut artifact
            c. Transducer angulation
            d. Central foreign body grasp
            e. Forceful foreign body grasp
            f. Tissue grasp vs. clean foreign body grasp
      ii. Hands on training-Turkey breast tissue model with mentored training
         1. Physicians will perform USFBR
            a. Mentored training with live removal of wood and metallic foreign bodies in tissue models.
            b. Train to proficiency
   c. Post test
      i. Each physician removes 5 wood and 5 metallic foreign bodies
      ii. Video documentation of post-test

iii. Written analysis of video documentation detailing the foreign body removal technique
iv. Written analysis of video documentation detailing the foreign body removal technique
    1. Time to removal
    2. Success/failure of removal attempt after 15 minutes
    3. Proper/errant alignment of insonation and instruments
    4. Proper/errant hand position and transducer position
    5. Proper/errant use of forceps in field of operation
    6. Proper/errant stepwise foreign body definition
    7. Proper/errant forceps grasp of foreign body
    8. Recognition/lack thereof-volume averaging artifact
    9. Recognition/lack thereof-oblique crosscut artifact

2. Session 2-4 will repeat quarterly training elements defined in Session 1

Part 3 is a clinical implementation study, documenting USFBR procedural parameters such as time of removal, incision size, type of foreign body, and fragmentation during removal, and success for failure of removal attempt, blunt vs. sharp dissection, complications, technical pitfalls encountered, time to return to function, time of wound healing, and subjective patient evaluation of the experience. Data will be recorded by the radiologist/physician performing the USFBR procedure. The approved SOW listed the clinical implementation study to begin in year one and continue into years 2 and 3 as military physicians are trained and competent in USFBR techniques, and deploying this care technology in their respective MTFs. Part 3 has been submitted to TAMC local IRB and we are waiting for notification of an approval. Once this approval is issued the protocol will be submitted for local IRB approval at NCH and final approval through the ORP HRPO. Veronica J. Rooks, MD, COL, MC, USA will serve as the PI at Tripler Army Medical Center (TAMC). William E. Shiels II, DO will be the Co-PI for part 3. Troy Koch, MD, CPT, MC, USA was not listed in the original SOW but was thought to join the research team at one time so his name was mentioned in the year 1 annual report. He is now not going to be part of the project due to conflict of time. His name has not been added to the study; no changes were submitted to the SOW and will not need to be submitted. Part 3 can not begin until part 2 is approved and the physicians are trained in USFBR. We will pursue optional future years if funding is available due to the delay in starting parts 2 and 3.

Part 3: Military Medical Center Clinical Implementation Study

I. Clinical implementation study at a minimum of one MTF, documenting USFBR procedural parameters such as time of removal, incision size, type of foreign body, fragmentation during removal, success for failure of removal attempt, blunt vs. sharp dissection, complications, technical pitfalls encountered, time to return to function, time of wound healing, and subjective patient evaluation of the experience.
II. Clinical comparison will be made with similar parameters, as possible, with patients who have undergone traditional surgical fragment removal (chart review and/or photographic documentation from patients undergoing both procedures).
III. Record referral source, indication, prior attempts at removal of respective foreign body
IV. Dr. Shiels and Nationwide Children's Hospital will provide parallel clinical state-of-the-art procedural and care algorithm development using ultra-high resolution sonography, with linear, compact linear, phased array, and convex linear transducers. Dr. Shiels and Nationwide Children's Hospital will provide quarterly, web-based state-of-the-art technology clinical and technical improvement updates. Dr. Shiels will provide annual on-site USFBR hands-on simulator procedural and technology update training at TAMC.
V. The PI or the research coordinator will visit the clinical implementation site a minimum of one time a year to manage data collection.

KEY RESEARCH ACCOMPLISHMENTS:

Part 1 was completed with success in year 1 using the tasks described in the approved SOW.

REPORTABLE OUTCOMES:

No manuscripts, abstracts, presentations or other reportable outcomes have resulted form this research at this time.

CONCLUSION:

The hypothesis for part 1 was proven partially correct. The hypothesis was that ultrasound guided foreign body removal (USFBR) is faster and more effective than open surgical removal, with smaller incisions. The results found that USFBR is more effective than open surgical removal, with smaller incisions. However the results also showed that the surgical method was faster. The results could have been affected by taking into account the differences in live tissue versus the dead tissue used with the cadaver thigh in this study.

During future work or another comparison between radiologists with percutaneous USFBR, conventional surgical foreign body removal, and surgical foreign body removal with wire localization some changes would be recommended. Natural colored wooden toothpicks would be a better choice than colored toothpicks that are easy to see in the cadaver tissue. Live tissue would alleviate the movement of the foreign body; but there would be no way to conduct a study on live patients with standardized implanting foreign bodies. A study could be done with live patients with existing foreign bodies but then there would not be any controls. Live patients would also have blood to make the operative portions of the study more life-like; however a researcher would not ever subject a patient to undue trauma from a surgical method if the percutaneous ultrasound guided foreign body removal technique were available.

The findings showed the percutaneous ultrasound guided foreign body removal technique to have much less tissue destruction than operative techniques; the incision size is also much smaller in this technique. This would result in a faster healing time if the foreign body removal was performed in a live patient. Sutures are not needed in the radiological method. The success rate was 100% for the percutaneous ultrasound guided foreign body removal technique. Where as the success rate for traditional surgical method and surgical with wire localization were only 78% and 89% respectively. The knowledge gained from this research demonstrates that USFBR is a more effective and less traumatic method of removing foreign bodies and should be readily implemented into the military system by training military physicians in part 2 with a clinical implementation in part 3.

REFERENCES:

Shiels WE II, Babcock DS, Wilson JL, Burch RA. Localization and Guided Removal of Soft-tissue Foreign Bodies with Sonography. AJR 1990; 155(6):1277-128.

Shiels II WE: Soft Tissue Foreign Bodies: Sonographic Diagnosis and Therapeutic Management. Ultrasound Clinics. October 2007. Vol. 2, Issue 2, 669-81.

Close JK, Shiels WE II, Foster JA, Powell DA: Percutaneous Ultrasound-guided Intraorbital Foreign Body Removal. Ophthal Plast Reconstr Surg. 2009 Jul-Aug; 25(4):335-7.

APPENDICES:

Appendix 1: Foreign Body Removal Record Form
Appendix 2: Cadaver Cohort Study Data Spreadsheet
Appendix 3: Cadaver Cohort Comparison Study-Incision size
Appendix 4: Cadaver Cohort Comparison Study-Removal Time
Appendix 5: Cadaver Cohort Study – Wound Closure (Number of Sutures)
Appendix 6: Cadaver Cohort Study - Overall Success

APPENDIX 1
Foreign Body Removal Record Form

Date:

Surgical procedure
Removal technique: ( ) Surgical - traditional surgical removal following skin marking of foreign body location

Cadaver thigh: ( ) #1
FB location ( ) #1 ( ) #2 ( ) #3

Cadaver thigh: ( ) #2
FB location: ( ) #1 ( ) #2 ( ) #3

Cadaver thigh: ( ) #3
FB location: ( ) #1 ( ) #2 ( ) #3

Surgical procedure
Removal technique: ( ) Wire localization – surgical removal of the foreign bodies following ultrasound guided placement of localization wires at the site of each foreign body.

Cadaver thigh: ( ) #4
FB location: ( ) #1 ( ) #2 ( ) #3

Cadaver thigh: ( ) #5
FB location: ( ) #1 ( ) #2 ( ) #3

Cadaver thigh: ( ) #6
FB location: ( ) #1 ( ) #2 ( ) #3

Radiological procedure
Removal technique: ( ) Percutaneous - interventional radiological ultrasound guided foreign body removal

Cadaver thigh: ( ) #7
FB location: ( ) #1 ( ) #2 ( ) #3

Cadaver thigh: ( ) #8
FB location: ( ) #1 ( ) #2 ( ) #3

Cadaver thigh: ( ) #9
FB location: ( ) #1 ( ) #2 ( ) #3

FB type: wood

Incision size (self report): ____
Incision size (video confirmation): ____

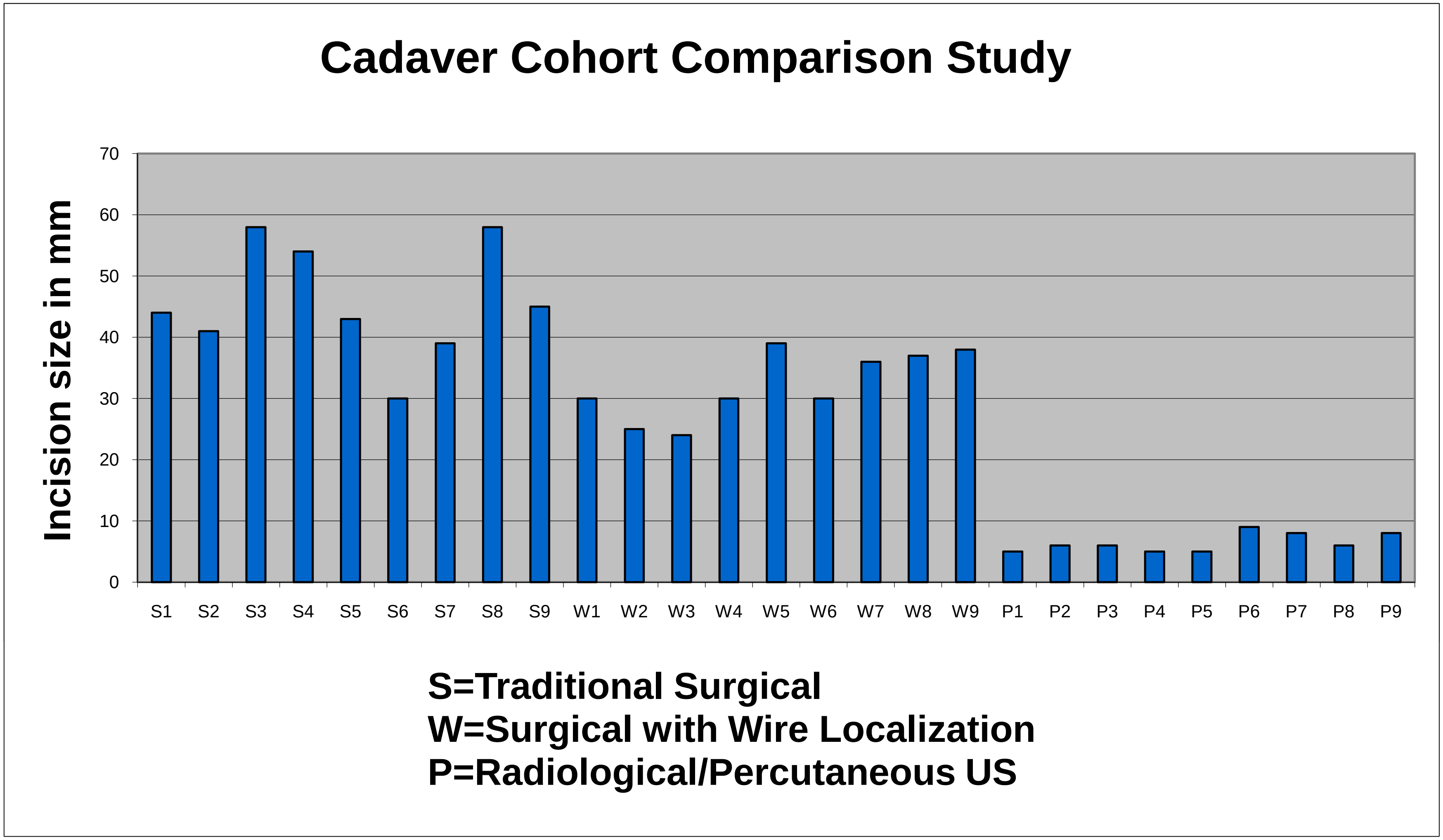
Time of procedure (self report): ____
Time of procedure (video confirmation): ____

Wound closure/number of sutures (self report): ________________________________
Wound closure/number of sutures (video confirmation): __________________________

Overall removal success: (self report): ____
Overall removal success: (video confirmation): ____________________________________

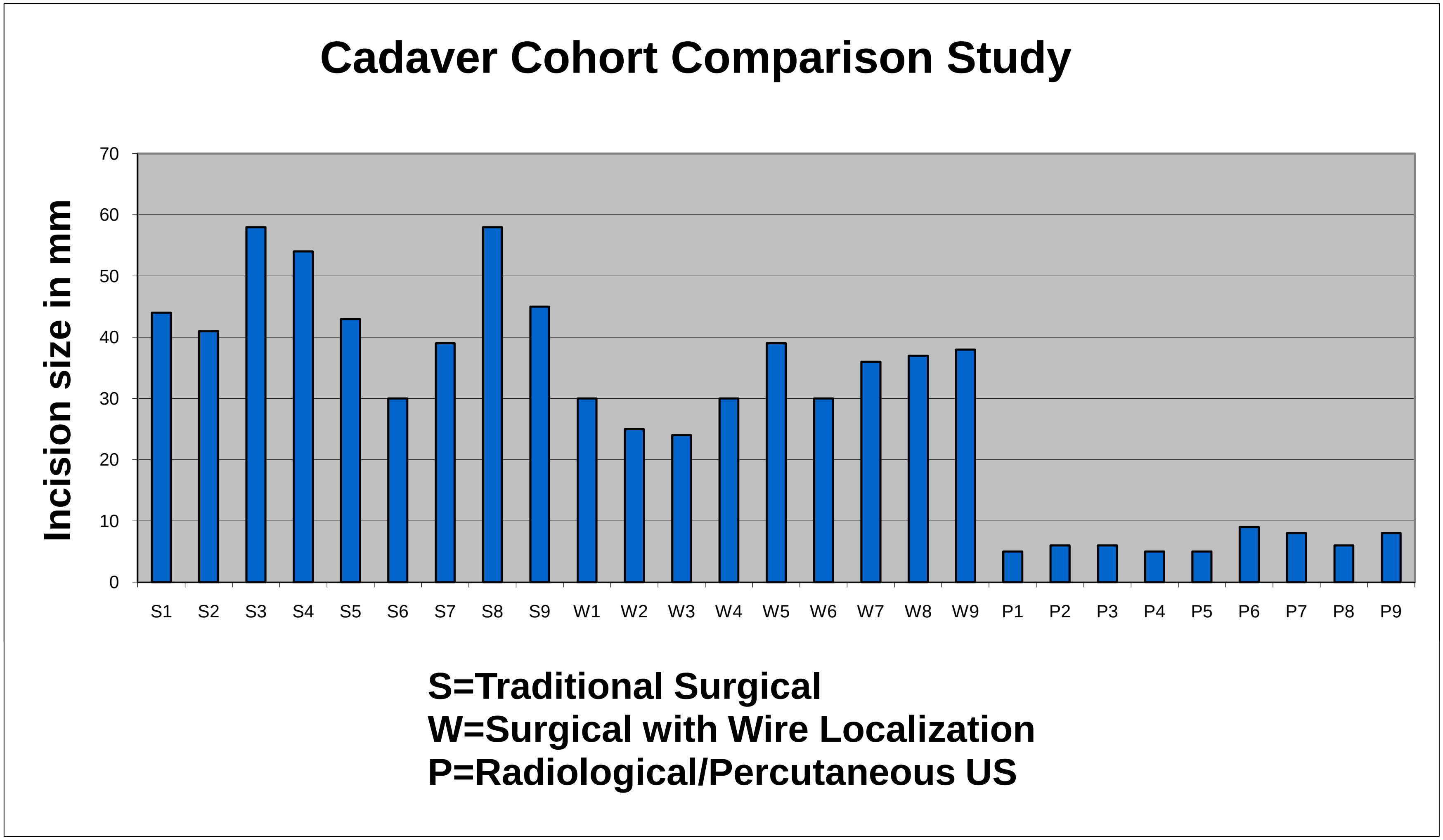
Procedural differences as noted by study coordinator from documentation during procedure and review of video documentation: Notes: (see back of page)

APPENDIX 2

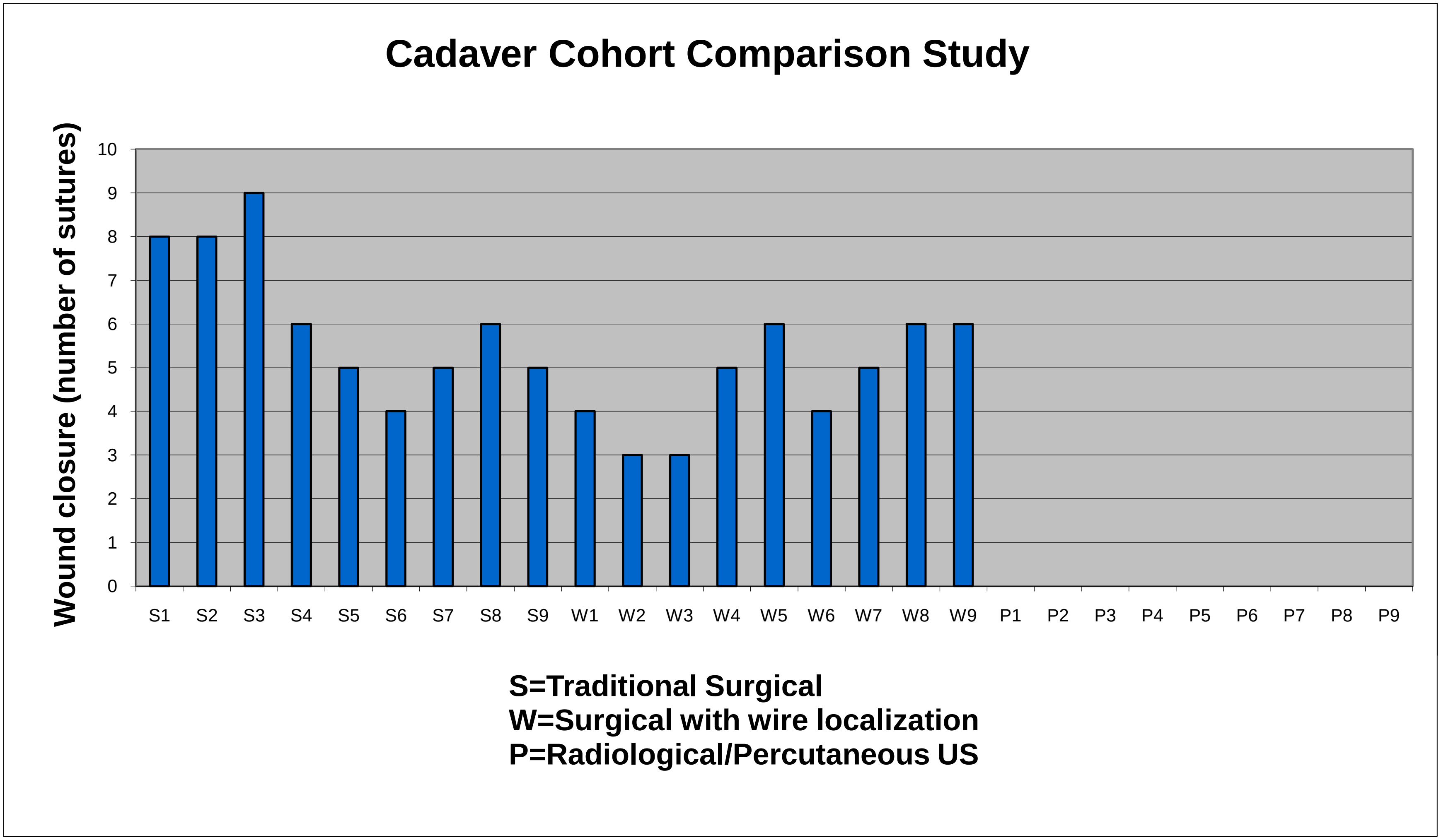


Cadaver Cohort Comparison Study
Incision size in mm
0
10
20
30
40
50
60
70
S1 S2 S3 S4 S5 S6 S7 S8 S9 W1 W2 W3 W4 W5 W6 W7 W8 W9 P1 P2 P3 P4 P5 P6 P7 P8 P9
S=Traditional Surgical
W=Surgical with Wire Localization
P=Radiological/Percutaneous US

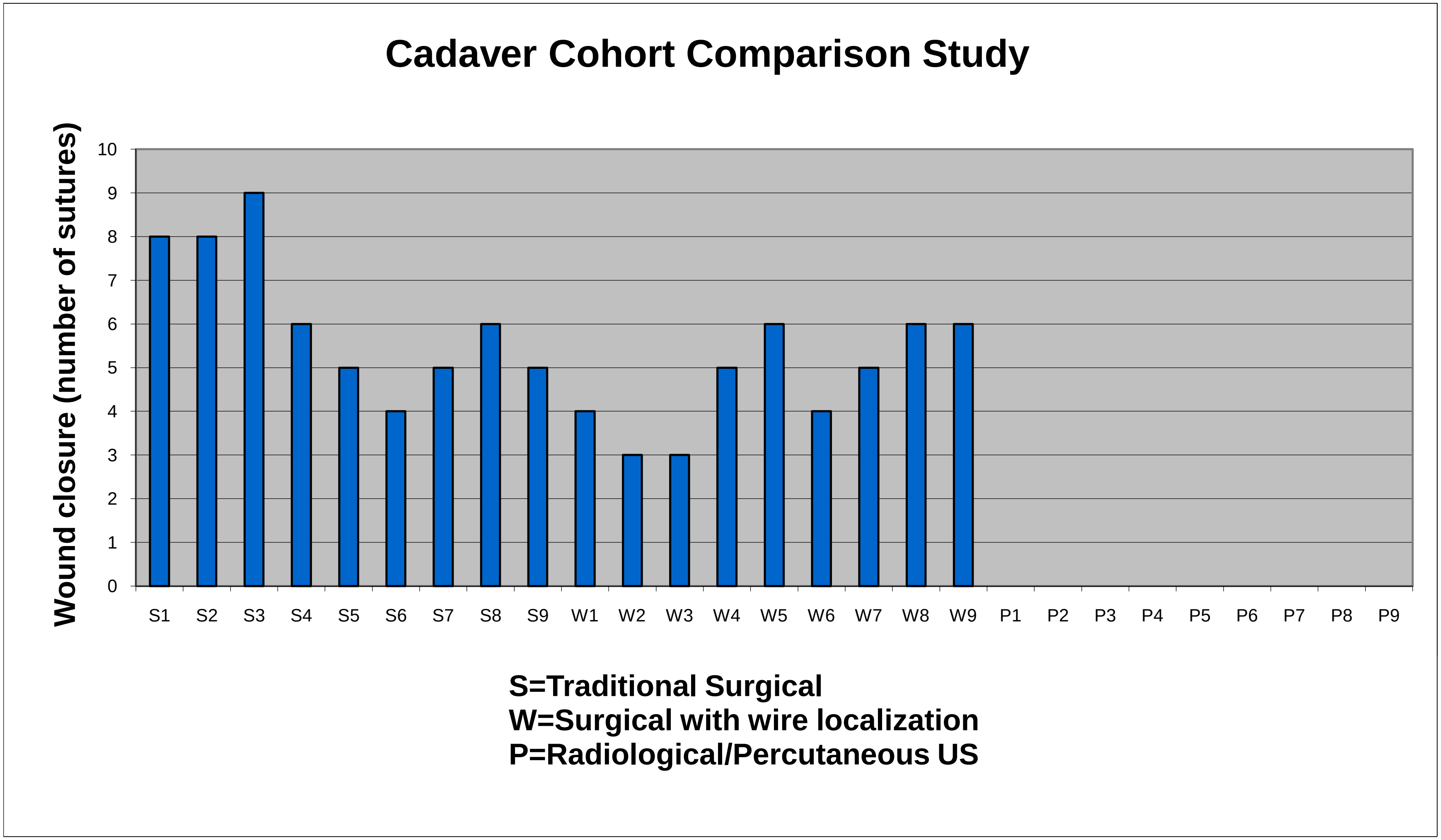
APPENDIX 3


Cadaver Cohort Comparison Study
Incision size in mm
70
60
50
40
30
20
10
0
S1
S2
S3
S4
S5
S6
S7
S8
S9
W1
W2
W3
W4
W5
W6
W7
W8
W9
P1
P2
P3
P4
P5
P6
P7
P8
P9
S=Traditional Surgical
W=Surgical with Wire Localization
P=Radiological/Percutaneous US

APPENDIX 4



Cadaver Cohort Comparison Study
Wound closure (number of sutures)
0
1
2
3
4
5
6
7
8
9
10
S1
S2
S3
S4
S5
S6
S7
S8
S9
W1
W2
W3
W4
W5
W6
W7
W8
W9
P1
P2
P3
P4
P5
P6
P7
P8
P9
S=Traditional Surgical
W=Surgical with wire localization
P=Radiological/Percutaneous US


Cadaver Cohort Comparison Study
Wound closure (number of sutures)
10
9
8
7
6
5
4
3
2
1
0
S1 S2 S3 S4 S5 S6 S7 S8 S9 W1 W2 W3 W4 W5 W6 W7 W8 W9 P1 P2 P3 P4 P5 P6 P7 P8 P9
S=Traditional Surgical
W=Surgical with wire localization
P=Radiological/Percutaneous US

Cadaver Cohort Comparison Study